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| 14. ABSTRACT<br>The purpose of this study is to examine a population-based intervention using preventive measures of a remote call-based asthma disease management program utilizing proactive education and monitoring. This intervention will be compared to a control population of pediatric asthma patients receiving printed education materials and usual care at three DoD military treatment facilities in a similar geographic region. Comparison will be made to examine differences in patient and caregiver quality of life (QOL), disease severity (as measured by reduced inhaled short acting beta agonist use), pulmonary function as measured by peak flow and spirometry (FEV1), and Emergency Department visits and hospital admissions. To date the study has obtained IRB approval, established and utilized the contracting organization to hire study staff and reimburse the selected disease management (DM) firm. Needed supplies and equipment were purchased. A research database was created. Rollout procedures visits to the sites and DM firm were completed as were subsequent quality assurance visits. The study population was identified, recruited and enrollment was completed with 451 patients. 398 patients completed the study and final data acquisition and analysis are underway. |                  |                          |                            |   |   |
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PRINCIPAL INVESTIGATOR: James M. Quinn, M.D.

CONTRACTING ORGANIZATION: The Geneva Foundation  
Tacoma, WA 98405

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# Introduction

**Background:** Call-center based disease management programs (CBDMP) are used in the commercial healthcare industry, however, they have not been utilized in the Military Health System (MHS). They provide population based proactive education and monitoring for specific disease states. Patients are educated and empowered to seek treatment according to nationally accepted guidelines for their particular condition. Asthma is the number one reason for childhood hospitalizations in the MHS, has a significant impact on missed school days, and impacts duty restrictions for asthmatic child caregivers. This study will conduct a benefit analysis of an alternative disease management (DM) process.

**Objective/Hypothesis:** That a CBDMP, applied to asthma, will:

- Improve patient and caregiver quality of life (QOL)
- Reduce disease severity, as measured by reduced inhaled short acting beta agonist use
- Improve patient condition as measured by Peak Expiratory Flow
- Reduce Emergency Department (ED) visits and hospital admissions

**Specific Aims:** This study will measure the impact of CBDMP, which promotes patient education and empowerment, on multiple factors to include; patient/caregiver quality of life, patient peak flow values, and utilization of MHS and MCSC healthcare resources. The study will assess the impact on an asthmatic population randomly selected from three military TRICARE Prime communities, to see if CBDMP improves patient health compared to a control group selected from the same three communities. It will also quantify cost savings/avoidance as a result of such programs.

## Body

THE ORIGINAL APPROVED STATEMENT OF WORK APPEARS IN BLACK. TEXT IN ITALICS DESCRIBES THE ACCOMPLISHMENTS ASSOCIATED WITH EACH TASK.

### STATEMENT OF WORK

All dates are from the time of grant acceptance. Assuming grant funds are not delayed.

Months 1-3: IRB review and approval, coordinate with Geneva Foundation for establishment of trust fund and trust fund disbursements processes. (Geneva has already agreed to be the trust agent). Purchase PC for study coordinator, prepare statement of work for DM firm bids.

*IRB approval has been obtained. The Geneva Foundation established the trust and has been disbursing funds as requested. The study coordinators all have computers. The statement of work for the Disease Management (DM) firm was completed*

Month 3: Geneva to hire program administrator, offer DM statement of work for DM for bid, identify asthmatics in three study locations. Purchase peak flow meters. Prepare and reproduce patient education materials, and informed consent work sheets. Contract Oracle data base administrator to establish database for research data collection. Contract peak flow meter data collection web site support.

*The program administrator and site coordinators have been hired. The DM statement of work was put out for bid. Asthmatics in the three study locations have been identified. Electronic peak flow meters have been purchased. Patient education materials and informed consent documents have been reproduced. A web-based Oracle data-base was determined to be both prohibitively expensive and in peril of violating at the time existing standards of privacy and systems security within the DoD computer systems and would with near certainty violate the evolving HIPPA and DoD systems security as identified at the time. An in-house security/privacy compliant Microsoft Access Database was created for research data collection. The company utilizing web based site support for peak flow meters went out of business. The peak flow company contracted is able to support electronic data transmission but not web based support.*

Months 2 – 4: Receive bids, select DM firm. Geneva to arrange for 1 additional study assistant to help with initiation of study, material distribution, and study participant recruitment and education. Coordinate data exchanges with DM firm and research group. Potential study population identified from available military and Foundation Health databases. Establish research database at Tricare Southwest. Travel to DM firm to make arrangement for rollout and data integration. Travel to study location to educate providers about the program that their patients may be randomly selected to enter.

*Bids were received and a DM firm was selected – National Jewish Medical and Research Center. The Geneva Foundation hired a coordinator at each site after approval and additional funding from PRMRP. Data exchange was coordinated with the DM firm. The potential study population has been identified via military and Foundation Health databases. Tricare Southwest has established a research database. Travel to the DM firm, arrangement for rollout and data integration was accomplished. Travel to the study sites with rollout education was accomplished.*

Months 1 - 12: PI visit to Texoma for brief provider education. Contact study participants, describe study and consent documents. Collect informed consents. Basic educational material and spirometer to all study participants. Collect baseline information and QOL. Randomized subjects to control or intervention group. Begin CBDMP support

Principle Investigator (PI) visit to Texoma for provider education and rollout was accomplished. Study participants have been contacted and enrolled. Informed consents have been signed and collected. Enrollment began in January 2003 and closed in December 2003 with 451 total patients enrolled. Educational materials have been given to all participants. In order to comply with national guidelines; the protocol was amended with IRB approval to distribute peak flow meters only to patients with persistent asthma (mild persistent, moderate persistent, severe persistent) and to defer peak flow distribution to mild intermittent asthmatics unless requested by any patient's healthcare provider. Anticipated savings and an IRB approved amendment allowed the purchase of a spirometer for each site to measure FEV1. Baseline QOL information has been obtained. Patients have been randomized and the DM firm has been implementing call-based disease management.

Months 1 – 24: Collect retrospective MCSC claims, CHCS encounter and medication on all study participants in both the intervention and control groups as they enter and continue with the program. DM intervention and prospective data collection begins. Data collection/enrollment will be for 12 consecutive months. Data transferred from DM firm and entered into research database. Research assistants to contact control groups and collect data every 6 months (QOL). Conduct patient satisfaction surveys for the intervention group when they complete the study. Make quality assurance visit to DM firm and study office in Texoma

To standardize the process of analysis and improve efficiency, claims, pharmacy, and provider visit analysis will be done at completion of the study for individual patients looking back two years (with separation of year one vs year two) rather than analysis at enrollment looking back one year and at completion looking back one year. Our study staff at the TRICARE lead agent pulled interim data and to test the quality and format of the data in the fall of 2004. Formatting and availability of some of the data were incomplete but much of the data pulled was adequate and accurate and entered into the database. In late 2004, the TRICARE leadagent for region VI ceased to exist in the rollover to the new TRICARE central region organizational structure. Another data pull was accomplished but its formatting and content have made it largely unusable. With the disappearance of TRICARE region VI we lost the personnel in that office supporting our grant. We have been working over the recent months to attempt to resurrect usable data from the final pull as well as to first find the source and get permission to access the claims and central pharmacy data that used to reside with region VI. This has been incompletely successful to date and we are attempting to merge the request with the possibility of using remaining personnel monies to contract the data acquisition but the legality and/or acceptability regarding policy are under review. We have monies remaining to support contracting help with final data acquisition and analysis and were granted a one-year no-cost extension for that purpose. DM intervention is complete and we have closed all three sites and brought the original CRF records and data to our central location. Interim quality assurance visits to DM firm (June 2003) and to sites in Texoma (June 2003, October 2003, June 2004, November 2004, June 2005) have been accomplished.

Months 15-27: Collection of last 12 months of healthcare resource utilization, QOL and PEF data (must wait 3 months post intervention for reliable claims data to be recorded)

As above, the look at closeout regarding healthcare utilization has been problematic. The QOL, PEF, and FEV1 data have been converted to computerized format and are ready for analysis on the 398 patients completing the study

Months 28-29: Final data analysis

*We are awaiting the cost and central pharmacy data prior to analysis..*

Months 29-30: Findings and conclusion write up.

*Pending above.*

## **Key Resesarch Accomplishments**

From first annual review:

- IRB approval obtained at both Wilford Hall Medical Center and Brooke Army Medical Center
- The Geneva Foundation established as contracting organization
- Study staff hired at each of the three sites
- Bids received and DM firm selected – National Jewish Medical and Research Center
- Study population identified via military and Foundation Health databases
- Electronic peak flow meters purchased
- Patient education materials and informed consent documents reproduced
- Research database established by Tricare Southwest
- Traveled to the DM firm to review and establish rollout procedures
- Traveled to three sites to review rollout and provide education/overview to primary care providers
- Study participants contacted and enrolled beginning January 2003 - 115 patients to date
- Patients randomized and DM firm performing call-based disease management
- Study participants contacted and enrolled with enrollment closed in December 2003 after enrolling 451 patients
- Seventy one participants have completed the study
- Electronic database has been modified and updated to capture all outcomes data for 6 month and 1 year/closeout visits
- Quality assurance visits have been undertaken to the DM firm (one to date) and to the sites (two to date)
- TRICARE lead agent has provided pharmacy data for participants that have completed the study and data is being entered
- TRICARE is engaged with the medical informatics staff to accumulate utilization and cost data on patients and to manipulate the format for most efficient analysis

New for this second annual review

- Patient enrollment, follow-up, and all patient driven data completed and closed out
- Drop-out and lost-to-follow-up rates remained low with 398 subjects completing the trial for a >88% retention
- Three clinical sites have closed and data collected with records centralized at lead site
- Adequate funds remained to allow for no-cost extention to finish data acquisition and analysis



## Reportable Outcomes

### Enrollment Data

| SITE              | Number intervention group/Number enrolled | Number completed <sup>2</sup> | Number withdrawn <sup>2</sup> | Number lost to follow-up <sup>2</sup> |
|-------------------|---|-------------------------------|-------------------------------|---------------------------------------|
| <b>Tinker AFB</b> | 71/142                                    | 114                           | 0                             | 28                                    |
| Ft Sill           | 77/154                                    | 146                           | 3                             | 5                                     |
| Sheppard AFB      | 77/155                                    | 138                           | 2                             | 15                                    |
| <b>Totals</b>     | <b>225/451</b>                            | <b>398</b>                    | <b>5</b>                      | <b>48</b>                             |

| Site         | Mild Intermittent (%) | Mild Persistent (%) | Moderate Persistent (%) | Severe Persistent (%) | Mean Age (yr) | Male (%) | Mean FEV1 (L) | Mean FEV1 (% Predicted) |
|--------------|-----------------------|---------------------|-------------------------|-----------------------|---------------|----------|---------------|-------------------------|
| Tinker AFB   | 32                    | 60                  | 8                       | 3                     | 12.53         | 68       | 2.32          | 101                     |
| Ft Sill      | 27                    | 39                  | 29                      | 5                     | 13.45         | 62       | 2.02          | 94.3                    |
| Sheppard AFB | 26                    | 32                  | 38                      | 4                     | 11.58         | 53       | 2.01          | 94.5                    |
| Totals       | 28                    | 43                  | 25                      | 4                     | 12.52         | 59       | 2.11          | 96.4                    |

## Conclusions

None

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